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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/554,996	05/24/2000	Mark T. Keating	HYDR-P01-002	4041
28120	7590	11/22/2005	EXAMINER	
FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			CHEN, SHIN LIN	
			ART UNIT	PAPER NUMBER
			1632	

DATE MAILED: 11/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/554,996

Applicant(s)

KEATING ET AL.

Examiner

Shin-Lin Chen

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-4, 6-14, 22-24, 26, 28-33, 35, 48-50, 56-63 and 65 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4, 6-14, 50, 56-59, 61, 62 and 65 is/are allowed.
- 6) ☒ Claim(s) 22-24, 26, 28-33 and 35 is/are rejected.
- 7) ☒ Claim(s) 48, 49, 60 and 63 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 May 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed 9-19-05 has been entered. Claims 1, 8, 9, 22, 48, 49, 56, 60-63 and 65 have been amended. Claims 27 and 67-69 have been canceled. Claims 1-4, 6-14, 22-24, 26, 28-33, 35, 48-50, 56-63 and 65 are pending and under consideration.

Double Patenting

1. Claims 48 and 49 are objected to under 37 CFR 1.75 as being a substantial duplicate of claims 60 and 63, respectively. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 22-24, 26, 28-33 and 35 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition comprising a tropoelastin or 7 repeats of the sequence of SEQ ID No. 1 (VGVAPG) or a method for preventing vascular restenosis by using said composition via direct administration of said composition to a targeted site *in vivo*, does not reasonably provide enablement for a method for treatment of a restenosis by delivering said pharmaceutical composition to a targeted site via any

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administration route *in vivo*, such as via a biocompatible support. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims and is repeated for the reasons set forth in the preceding Official action mailed 3-17-05. Applicant's arguments filed 9-19-05 have been fully considered but they are not persuasive.

Applicants amended claims 60-62 to read on an elastin-based composition consisting of a polypeptide consisting of (i) an amino acid sequence identical to SEQ ID No. 3, (ii) an amino acid sequence identical to SEQ ID No. 2, or (iii) a peptide fragment of six repeats of the hexameric sequence represented by SEQ ID No. 1. This is not found persuasive because of the reasons set forth in the preceding official action mailed 3-17-05 and the following reasons. The specification fails to provide adequate guidance and evidence for how to treat restenosis via direct delivery of the pharmaceutical composition having the elastin-based composition to a targeted site *in vivo* so as to provide therapeutic effect in treating restenosis *in vivo*. The specification discloses use of a human tropoelastin or 7 repeats of the sequence of SEQ ID No. 1 (VGVAPG) for preventing vascular restenosis *in vitro* or *in vivo*. However, preventing restenosis is different from treating restenosis because the pathological state of the cells before occurrence of restenosis is different from that of the cells after the occurrence of restenosis. The specification fails to provide evidence whether direct delivery of the claimed elastin-based composition would be able to ameliorate the symptom of restenosis *in vivo*. Thus, claims 22-24, 26, 28-33 and 35 remain rejected under 35 U.S.C. 112, first paragraph.

Conclusion

Claims 22-24, 26, 28-33 and 35 are rejected. Claims 48, 49, 60 and 63 are objected.

Claims 1-4, 6-14, 50, 56-59, 61, 62 and 65 are in condition for allowance.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shin-Lin Chen whose telephone number is (571) 272-0726. The examiner can normally be reached on Monday to Friday from 9:30 am to 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for this group is (571) 273-8300.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Shin-Lin Chen, Ph.D.

A handwritten signature in black ink, appearing to read 'S. Chen', is located in the lower right quadrant of the page.